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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/216,506	03/22/1994	C. RICHARD SCHLEGEL	010091001	8196
909 7590 06/24/2010 PILLSBURY WINTHROP SHAW PITTMAN, LLP P.O. BOX 10500 MCLEAN, VA 22102				
EXAMINER				
MOSHER, MARY				
ART UNIT		PAPER NUMBER		
1648				
MAIL DATE		DELIVERY MODE		
06/24/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

08/216,506

Applicant(s)

SCHLEGEL ET AL.

Examiner

Mary E. Mosher

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 67, 69-77 and 79-91 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 67, 69-77 and 79-91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/C)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Transitional After Final Practice

Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.129(a). Applicant's first submission after final filed on March 8, 2010 has been entered.

Interference

Claims 67-73, 75-86, 88-91 remain rejected on the grounds of interference estoppel, being patentably indistinct from the claims lost in interference 104776, for reasons of record.

Applicant argues that the claims which were lost in the interference were directed to a genus, and the present claims are directed to a species within the genus. Because the prior art taught away from producing HPV L1 protein recombinantly, in the absence of HPV L2 protein, the claimed species is patentable over the genus defined in the Frazer claims. The key prior art, Zhou et al (Virology 185: 251-257, 1991) taught that co-expression of L1 and L2 was necessary to obtain HPV virus-like particles. The examiner does not dispute the teachings of the 1991 Zhou publication.

However, in the interference, in the claims corresponding to the count, Frazer claim 65 involved "expressing papillomavirus L1," and Frazer claim 73 involved "expressing papillomavirus L1 and L2." It must be concluded that "expressing papillomavirus L1 in the absence of L2" was an obvious species in

Art Unit: 1648

the context of this interference, because this species is the only difference between "expressing L1" and "expressing L1 and L2." Also in the context of the interference, the recitation of "conformational" elements in the Schlegel claims did not render the Schlegel claims distinct from the count. Therefore, it is maintained that the current claims are not patentably distinct from the claims lost in interference proceedings.

Claim Rejections - 35 USC § 112

Claims 67, 69-77, 79-91 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for L1 protein, does not reasonably provide enablement for fragments of L1 including conformational epitopes, for reasons of record.

Applicant argues that the specification teaches on pages 11-16, though means know to those skilled in the art, whether a protein or fragment is antigenic and has conformational epitopes present on intact HPV virions, for example by contacting with known conformational antibodies. While there was routine knowledge in the art regarding how to test for conformational epitopes in a protein or fragment, there was not corresponding routine knowledge on what modifications one could make and successfully obtain fragments with the desired conformational epitopes. As discussed in the previous Office action, the nature of conformational epitopes involves complex interactions between structures formed during folding and assembly, and a high degree of unpredictability existed regarding the effects of modifications such as truncations. Considering the state

Art Unit: 1648

of the art on the filing date in 1994, the absence of direction in the specification regarding conformational epitope-bearing fragments, the contemporary inability to predict the effects of any mutation upon the formation of conformational epitopes, and the scope of working examples limited to full-length L1 protein, it is maintained that undue experimentation would have been required to enable the full scope of the invention as claimed.

Claims 67, 69-77, 79-91 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a "written description" rejection directed at the "fragment" which "includes conformational epitopes present on L1 protein on the surface of intact human papillomavirus virions."

Applicants did not argue this rejection. Therefore the rejection is maintained.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.129(a) and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.129(a).

Art Unit: 1648

Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the submission under 37 CFR 1.129(a). See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher whose telephone number is (571)272-0906. The examiner can normally be reached on varying dates and times; please leave a message.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zach Lucas (Acting SPE) can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1648

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher/
Primary Examiner, Art Unit 1648

6/21/10